

Attorney Docket No.: **KUZ-0022**
Inventors: **Ito et al.**
Serial No.: **10/527,710**
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REMARKS

Claims 1-10 were pending in the instant application. Claims 1 and 8 have been amended. Claims 6 and 7 have been canceled without prejudice. New claims 11 through 19 have been added. Support for these amendments is provided in the specification at page 7 and page 12 and in the original claims. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejections under 35 U.S.C. 103(a)

The Examiner has maintained the rejection of claims 1-3 and 7-9 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866) in view of Tsuruda et al. (CA 2 424 579).

The Examiner has maintained the rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (U.S. Patent 4,031,894).

The Examiner has maintained the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (U.S. Patent 5,750,136).

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The Examiner has maintained the rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Higo et al. (U.S. Patent 5,866,157).

The Examiner has maintained the rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Zafforini (U.S. Patent 3,598,122) and further in view of Kochinke (U.S. Patent 5,350,581).

Applicants respectfully traverse these rejections.

Applicants have amended claim 1 to recite an adhesive patch for maintaining a long-term drug efficacy comprising a backing layer and a pressure-sensitive adhesive layer formed on one side thereof, wherein the pressure-sensitive adhesive layer consists essentially of fentanyl as an active ingredient, a pressure-sensitive adhesive base, and a tackifier resin, wherein the pressure-sensitive adhesive base comprises polyisobutylene and a styrene/isoprene/styrene block copolymer, the proportion of the polyisobutylene in the adhesive base being 8 to 15 wt.%, and a ratio of a concentration of the polyisobutylene to that of the styrene/isoprene/styrene block copolymer being from 2:3 to 3:2, and wherein the tackifier resin is an alicyclic

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saturated petroleum resin and a proportion of the tackifier resin is from 40 to 50 wt.%. Claim 8 has also been amended to recite the tackifier resin is an alicyclic saturated petroleum resin and a proportion of the tackifier resin is from 40 to 50 wt.%. Support for these amendments is provided in the specification at page 7, lines 9-17 and in claims 6 and 7, now canceled without prejudice.

Incorporation of subject matter of claim 6 into claims 1 and 8 renders moot the rejection of claims 1-3 and 7-9 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866) in view of Tsuruda et al. (CA 2 424 579); the rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (U.S. Patent 4,031,894); the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (U.S. Patent 5,750,136); and the rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Zafforini (U.S. Patent 3,598,122) and further in view of Kochinke (U.S. Patent 5,350,581).

Further, Applicants respectfully disagree that the combination of Chono et al. in view of Tsuruda et al. and

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further in view of Higo et al. (U.S. Patent 5,866,157) renders obvious the instant claimed invention.

MPEP 2144.05 is clear; if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. See also *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Chono et al. teaches a very broad range of numerous tackifiers from 0.1% to 70%(w/w), more preferably 5 to 50%(w/w), and most preferably from 10 to 35%(w/w). See col. 3, lines 56-60.

Tsuruda et al. also teaches a very broad range of a non-specific tackifier from 5-50% by mass. See claim 10.

Higo et al. also teaches a very broad range of tackifying resin of 10 to 70% (w/w/). See col. 2, line 50-51.

Accordingly, a very large number of adhesives are encompassed by the combined teachings of Chono et al. Tsuruda et al. and Higo et al.

In contrast, the instant claims have been amended to be drawn to adhesives comprising a specific tackifier resin of

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alicyclic saturated petroleum resin in the narrow range of 40 to 50 wt.%.

In no way does the broad genus of adhesives disclosed by the cited combination of references render obvious the instant claimed invention.

Further, MPEP 2144.05 is also clear in that Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). At page 7 of the instant application it is taught that the concentration of the tackifier resin is not more than 50 wt.% to prevent reduced adhesion to the skin due to the result that the adhesive mass becomes too hard and not less than 40 wt. % to obtain sufficient pressure sensitive adhesive strength suitable for long-term administration. Showing the criticality of this narrow range of alicyclic saturated petroleum resin tackifier as

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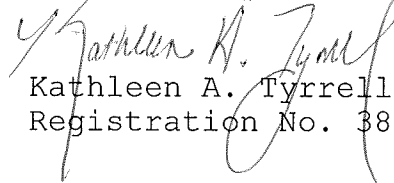
preventing reduced adhesion due to hardness while maintaining sufficient adhesive strength for long-term administration clearly rebuts any *prima facie* of obviousness over the broad teachings of the cited combination of art.

Withdrawal of all rejections under 35 U.S.C. 103(a) is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Actions of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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